115 CMR 10.00: RESEARCH

Section
10.01: Authority
10.02: Definitions
10.03: Scope
10.04: Research Review Committee of the Department
10.05: Research Proposals
10.06: Research Review
10.07: Consent Procedures
10.08: Research Approval
10.09: Expedited Review
10.10: Complaint
10.11: Funding for Research
10.12: Sanctions

10.01: Authority

The Department is authorized by M.G.L. c. 19B, §§ 1, 14 and 18 and M.G.L. c. 123B, §2 to regulate research activities concerning mental retardation or involving individuals with mental retardation conducted in the Commonwealth. 115 CMR 10.00 also is promulgated in conformity with Part 46 of Title 45 of the Code of Federal Regulations (45 C.F.R. 46).

10.02: Definitions

As used in 115 CMR 10.00, the terms listed below have the following meanings:

Committee means the Research Review Committee of the Department of Mental Retardation.

Guardian means with respect to persons under the age of 18 years, a natural or adoptive parent, or the individual or agency with legal guardianship of the person; and with respect to persons 18 years of age and older, the individual, organization or agency, if any, that has been appointed legal guardian of the person found to be incompetent by a court of competent jurisdiction. If a guardianship has been limited in any way by the court, the guardian's informed consent must be obtained only in those cases where a decision regarding participation in the research falls within the scope of the limited guardianship.

Informed Consent means the knowing consent voluntarily given by a participant (or if the participant is legally incompetent, by his guardian, if applicable) who can understand and weigh the risks and benefits of the proposed research for the participant.

Minimal risk means that the risk of physical or psychological harm or discomfort anticipated in the proposed research are not greater, in terms of probability and magnitude, than those ordinarily encountered in daily life.

Research means a systematic investigation designed to develop or contribute to generalizable knowledge and involving access to human subjects or private information, but shall not include:

(a) any nonexperimental activity, such as diagnosis, preventive treatment and therapy, designed solely to enhance the well being of a particular individual;

(b) any collection of information by the Department or its designee, or by an authorized federal or state governmental entity, for any purpose related to the operation, administration or management of the Department;

(c) any compilation or study of information, including information obtained through the interview of individuals, specifically designed by the Department or its designee (or a provider) for the purpose of evaluating the quality or availability of services, or opportunities or needs of persons eligible to receive or receiving services from the Department (or receiving services from the provider).

(d) any survey procedures, except where responses are recorded in such a manner that the survey participants or individuals receiving services from the Department can be identified, directly or through identifiers linked to the survey participants or to the indivi-

10.02: continued

duals; provided that all surveys shall be submitted to the Committee for a determination as to whether such surveys are exempt from Committee review.

Activities which meet this definition constitute research for purposes of 115 CMR 10.00, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration projects may include research activities that would require review by the Research Review Committee.

Participant means a person, whether or not such person is served by the Department, about or from whom an investigator conducting research will obtain data through intervention or interaction with the person, or other through private information.

Private information means any information concerning an individual which because of name, identifying number, mark, or description can be readily associated with a particular person, or information which has been provided for a specific purpose by an individual and which the individual can reasonably expect will not be made public, or which is about his/her behavior occurring in a context in which an individual can reasonably expect that no observation or recording is taking place.

10.03: Scope

(1) The provisions of 115 CMR 10.00 apply to any research, regardless of the source of funding, which meets one or more of the following conditions:

(a) any research activity that will take place at an office of the Department, a facility or a location where the provision of services or supports is purchased or subject to regulation by the Department;

(b) a person receiving services or supports provided or purchased by the Department is a participant, unless the research in no way involves the Department or any provider;

(c) the research involves disclosure by the Department or provider of private information.

(2) No research within the scope of 115 CMR 10.03 may be conducted without the prior review and approval as required by the provisions of 115 CMR 10.00.

(3) No research project may be conducted which has been disapproved or terminated by the facility director, regional director, or head of the provider, as appropriate, or by the Commissioner or the Research Review Committee.

10.04: Research Review Committee of the Department

(1) Membership.

(a) The Research Review Committee shall have at least five members, appointed by the Commissioner, who have expertise and experience in relevant areas to promote complete and adequate review of research activities subject to 115 CMR 10.00. Membership should reflect a diversity in racial and cultural backgrounds and shall not consist entirely of men or entirely of women.

(b) The membership shall include one attorney, one physician, one Ph.D. level psychologist, one person receiving services provided or purchased by the Department or family member of such a person, and one individual who is neither employed by nor receives funds directly or indirectly from the Department and who is not part of the immediate family of a person employed by or receiving funds directly or indirectly from the Department.

(c) Additional members may be appointed from time to time for regular terms.

(d) The members shall serve without compensation and shall be special state employees for the purposes of tort claims and conflicts of interest.

(2) Term of Office. Members of the Research Review Committee shall be appointed to terms of office as follows:

(a) Upon the establishment of the Committee, the Commissioner shall appoint members to a term of one to three years;

10.04: continued

(b) Upon the expiration of the term of any member, the Commissioner shall appoint a successor for a term of three years;

(c) In the event a vacancy occurs prior to the expiration of the applicable term, the Commissioner may appoint a person to serve the remainder of the unexpired term.

(3) Removal. The Commissioner, after consultation with the other Committee members, may remove a person as a member. Grounds for removal shall include serious disregard or gross neglect of responsibilities or other actions which are in violation of the regulations or policies of the Department or the procedures of the Committee.

NON-TEXT PAGE

10.04: continued

(4) Powers and Duties. The Research Review Committee shall have the following powers and duties:

(a) To hold regular meetings during each year at which a quorum consisting of a majority of the appointed members must be present to act on any research proposal requiring the Committee's attention;

(b) To review research proposals and conduct continuing review of research projects;

(c) To develop procedures and guidelines related to its duties and consistent with the Department's regulations and policies;

(d) To approve, approve with conditions, defer discussion pending receipt of additional information, or disapprove by a majority vote of the members present at the meeting, research proposals and projects;

(e) To suspend or terminate approval of research that is not being conducted in accordance with the Committee's requirements or approval, or that has been associated with unexpected harm to participants;

(f) To maintain written minutes of every meeting of the Committee which will record the names of the members present, those absent, the names of non-members who are present and the numerical vote of the Committee members on each research proposal and research project reviewed.

(g) To maintain a permanent record which will list, in chronological order, every research proposal submitted to the Committee and contain the following information on each proposal: name/title of the research project, name and address of the investigator, date of receipt, date of approval/disapproval, date of subsequent annual review, and date of withdrawal or termination.

(h) To invite, at its discretion, experts in special areas to assist in the review of a particular research project which requires expertise beyond or in addition to what is available on the Committee. These experts may not be associated with the proposed research in any way and may not vote with the Committee.

(i) To serve, subject to the approval of the U.S. Department of Health and Human Services, as the Institutional Review Board of the Massachusetts Department of Mental Retardation.

10.05: Research Proposals

(1) A research proposal must be submitted to the Research Review Committee for any research covered by 115 CMR 10.00. The Committee, by written communication, will notify the researcher of the number of copies to be submitted and the time lines for submission.

(2) Each proposal must include, at a minimum, the following information about the proposed research:

(a) identification of the investigators conducting the research and their credentials;

(b) purposes and objectives of the research;

(c) location(s) where the project will be conducted;

(d) the private information or participants to which access is sought, including a description of the type of private information or the manner of access to the participants and the number of participants who will be involved in the study;

(e) the direct benefits of the research to the participants, or the potential for contributing new knowledge that might benefit persons with mental retardation or their families or the field of mental retardation;

(f) description of any foreseeable cost(s) to the individual as a result of participating in the research (*e.g.* loss of wages, travel and parking expenses, lunch, *etc*.), and any compensation or reimbursement that will be offered to the participant to offset such cost(s).

(g) justification for the participation of persons with mental retardation and description of why the research questions cannot be answered through the use of persons without mental retardation;

(h) description of the research methods and procedures to be used;

(i) duration of the project;

10.05: continued

(j) identification of all foreseeable risks (physical, psychological, social, economic, legal or other), and a full discussion of their likelihood and potential severity;
(k) discussion of why risks to participants may be considered reasonable in relation to the anticipated benefits to participants and in relation to the importance of the knowledge that may reasonably be expected to result.
(l) procedures to be followed in the event there is any adverse effect to a participant;
(m) description of how the research may affect the care or treatment of the participant during the research and after the research has ended;
(n) information to be provided to the participant and their guardian, if applicable, prior to obtaining informed consent and a copy of the informed consent form to be used, where applicable;
(o) safeguards for confidentiality to be maintained;
(p) manner of disposal of the private information at the termination of the project;
(q) type of final product to be produced, its intended use and the manner of dissemination or publication, where applicable;
(r) where applicable, disclosure of intent to establish copyright, patents, or any other rights to the product and disclosure of the organization or persons in whom such rights are vested;
(s) a budget showing the projected expenditures and sources and amounts of funding for the project;
(t) the method to be used for the recruitment of participants and copies of any advertisement or written material to be employed; and
(u) where applicable, the manner in which the investigators intend to rely on Department or provider resources for assistance in conducting the research, collecting data, or providing private information.

(3) At the time the proposal is submitted, the investigator(s) must also submit to the Research Review Committee evidence of favorable peer review.
(a) For investigators (including students) affiliated with a hospital or university, the requirement for evidence of favorable peer review shall be met by submission of a copy of written approval of the proposal by the hospital's or university's institutional review board;
(b) For investigators who are not affiliated with a hospital or university, the requirement for evidence of favorable peer review shall be met by submission of three letters of approval of the proposal from three independent peers knowledgeable in the field of the proposed research.

10.06: Research Review

(1) The Research Review Committee shall review each research proposal for the primary purpose of protecting the rights and welfare of participants.

(2) The Committee must consider, as part of the review, the impact the proposed research may have on the participants in terms of health and physical safety, confidentiality and privacy, human dignity, self-determination and freedom of choice, care and treatment, fairness in selection of participants, freedom from undue discomfort, distress and deprivation, and such other interests that may be implicated by the particular research project.

(3) The Committee must further consider, in determining whether the foreseeable risks to the participants are reasonable in relation to anticipated benefits, available relevant clinical experience and expertise, existing knowledge of relevant research findings, canons of professional conduct and professional ethics, applicable laws, policies and procedural guidelines, standards of scientific methodology in the conduct of such research, the scientific merit of the research, the potential value of the research in the advancement of knowledge and the necessity or importance that persons receiving services from the Department are participants if the research involves individuals.

10.06: continued

(4) The Committee may require the research investigator or other staff persons involved in the conduct of the research to appear before the Committee to address the proposal. The Committee may require also the submission of additional documentation and materials which it deems appropriate for consideration before reaching a decision on the proposal.

(5) The Committee may appoint an advocate for the participants of a research project. The advocate shall provide counseling, assistance, and advocacy to individuals with respect to their participation in the research. No member of the Committee and no research investigator may be appointed as an advocate. The Committee shall be responsible for informing participants of the name and address of the advocate when one has been appointed.

10.07: Consent Procedures

(1) The consent procedure set out in 115 CMR 10.07 is applicable to all research. The content of the written consent form and the manner in which such consent will be sought shall be part of the Committee's review of the research proposal.

(2) The consent form must be written in language understandable to the participant and the guardian, if applicable. The form may not include any waiver of a participant's rights or any exculpatory language absolving the investigator, the sponsor, the Department, the program or their agents from liability for research-related injury. The form must provide the following information to each prospective participant and their guardian, if applicable:

(a) a statement that the study involves research, what is expected of the participant, with a full explanation of the purposes and objectives of the research;

(b) the basis for selection of the participant and the expected duration of the individual's participation;

(c) a description of the procedures to be followed and the identification of any procedures which are experimental;

(d) a description of any reasonably foreseeable risks or discomforts to the participant, their expected severity and duration;

(e) a description of any benefits to the participant or others which may reasonably be expected from the research;

(f) a statement describing how confidentiality of records and privacy of participants will be maintained;

(g) a description of any appropriate alternative procedures or courses of treatment that could be used in lieu of the experimental procedure, or if there is no alternative procedure;

(h) an offer to answer any questions concerning the procedures and the participant's rights and a statement of whom to contact and how for further information;

(i) a statement that participation is voluntary and the individual shall be informed, both verbally and in writing, that he or she is free to withhold consent or to withdraw consent and to discontinue participation in the research at any time without penalty or loss of benefits, services or supports which the individual is otherwise receiving;

(j) if the prospective participant is an individual receiving services provided or purchased by the Department or a family member of such an individual, a statement that mental retardation services to the individual do not depend on participation by the individual or family member in the research;

(k) where applicable, a description of any controlled substance as defined in the Massachusetts Department of Public Health regulations implementing M.G.L. c. 94, and any other substances to be used, and their anticipated effects, side effects and interactions. The description must be in language understandable to the prospective participant or guardian.

(3) A copy of the consent form, as approved by the Committee, must be given to each participant and his or her guardian, if applicable. The Committee may require a witness to be present at the time consent is sought, unless 115 CMR 10.08(2) *Additional Requirements*, applies.

10.07: continued

(4) Notwithstanding the consent of the guardian, an individual's participation in a research project must cease if the individual objects, by verbal or nonverbal means, to participation.

(5) The Committee may approve a modified consent form, but only if it finds and documents that all of the conditions listed in 115 CMR 10.07(5)(a) through (c) are met.

(a) The proposed research involves no more than minimal risk of social, psychological, or physical harm to the participant;

(b) A full explanation of the purpose(s) or objective(s) of the research before its completion would compromise or invalidate the study;

(c) The consent form provides the following information to each prospective participant and their guardian, if applicable:

1. a statement that the study involves research;
2. a general description of the nature of the research;
3. a statement that some aspects of the research purpose(s) or objectives are being withheld from the participant;
4. a statement that after the individual's participation in the research, the participant will be provided a written full explanation of the research purpose(s) and objective(s);
5. a statement that the individual agrees to participate in the research in the absence of a full explanation of the purpose(s) and objective(s) of the research study.

(6) The consent procedures described in 115 CMR 10.07(1) through 10.07(5) do not apply to a research project involving access to private information, but only if the Committee finds and documents that:

(a) the research consists of the study of historical records, and the researcher presents plans to protect the confidentiality of the information and to preclude the identification of particular individuals; or,

(b) the research consists of a review of records for the sole purpose of extracting information for a demographic or statistical study in which no person can be identified.

(7) Where a research investigator wishes to utilize the consent procedure described in 115 CMR 10.07(5) or (6), he or she must submit to the Committee, as part of the research proposal submission, specific and detailed reasons for seeking such consent procedure. The Committee may impose such conditions as it deems appropriate to safeguard the rights and welfare of the participants. Such conditions may include the appointment of advocates and monitors and stringent procedures to protect the confidentiality of personal information.

10.08: Research Approval

(1) Basic Requirements. Before any research covered by these regulations may be approved by the Research Review Committee, the research proposal must satisfy all of 115 CMR 10.08(a) through (f):

(a) selection of participants is equitable to the extent practicable by the objectives of the research;

(b) risks to participants are minimized by using procedures consistent with sound research design and which do not present unnecessary risks to the participants;

(c) risks to participants are reasonable in relation to anticipated direct benefits to participants and importance of the knowledge to be gained;

(d) informed consent will be sought and documented in accordance with and to the extent required by 115 CMR 10.07;

(e) the research provides for the protection of the participant's privacy and the confidentiality of private information; and

(f) where appropriate, the research provides for the safety of participants through monitoring procedures and corrective interventions.

(2) Additional Requirements. For certain types of research as described in 115 CMR 10.08(a) through (c), the research must meet additional requirements before the Research Review Committee may approve the project.

(a) If the research involves more than a minimal risk of physical or psychological injury to participants, then:

10.08: continued

1. the probability and magnitude of the anticipated benefit for each participant as a result of the research must equal or exceed such risk of injury; and,

2. where applicable, there is specific authorization by a court of competent jurisdiction for any individual not competent in fact of consent to participate in such research; and,

3. the additional consent and review procedures set out in 115 CMR 10.08(3) and (4) are met.

(b) If the research involves the administration of an experimental drug to a participant, then:

1. the use of the drug must be approved for trial in human beings by the Federal Food and Drug Administration;

2. the additional consent and review procedures set out in 115 CMR 10.08(3) and (4) are met; and,

3. the procedures and requirements of the Massachusetts Department of Public Health that are applicable to research involving new drugs are met.

(c) For any research project which the Commissioner, in his or her discretion, determines additional safeguards are required, one or more of the following requirements must be met:

1. the additional review procedure set out in 115 CMR 10.08(3); or,

2. the additional consent procedure set out in 115 CMR 10.08(4); or,

3. such other measures as the Commissioner, or his or her designee, determines appropriate to protect participants.

(3) Additional Review Procedure. The Commissioner shall designate a mental retardation professional to participate as a consultant to the Research Review Committee. This professional shall take such steps as he or she determines appropriate to review and monitor the risks and benefits to the participants. In addition, if the mental retardation professional determines that the risk-benefit requirements are not met for a particular individual, participation of the individual in the research shall terminate.

(4) Additional Consent Procedure. A witness appointed by the Research Review Committee must be present when consent is obtained for each participant, and the witness must determine that the investigator has obtained informed consent for that participant. The witness must be a person whose training and experience are sufficient for him or her to determine whether the consent of the prospective participant is informed. The Committee may appoint more that one witness for the research project.

(5) Notification. Within ten days of approving a research project, the Research Review Committee shall notify and send a copy of the research proposal and Committee minutes to the Commissioner, and where applicable, to the facility director or regional director and head of the provider with jurisdiction over the facility or program where the research activity will be conducted.

(6) Notwithstanding approval of the research by the Committee, the facility director, or the regional director or the head of the provider with jurisdiction over the site where the research is proposed to be conducted, or the Commissioner, may at any time take any of the following action with regard to the research:

(a) terminate the research, if he or she determines that it is too disruptive or burdensome on the programs involved or is not in the interest of the Department or the provider;

(b) impose additional conditions on the research;

(c) delay the initiation of research until further review is completed;

(d) suspend the research temporarily pending further investigation or other action.

(7) A statement of the reason(s) for the action shall be furnished promptly to the investigator(s). Any action taken pursuant to 115 CMR 10.08(6) is final and not subject to further review, judicial or otherwise.

10.09: Expedited Review

(1) The expedited review procedure is a review of a research proposal by the chairperson or a subgroup of the Research Review Committee. The reviewer may exercise all of the authorities of the Committee except disapproval of the research. A research activity may be disapproved only after review by the full Committee in accordance with the applicable requirements set out in 115 CMR 10.00.

(2) The expedited review procedure is permitted only for research which:

(a) seeks access only to private information;

(b) represents only minor changes to previously approved research, to be implemented during the period for which approval is authorized.

(c) the research consists of the study of historical records; or

(d) the research consists of a review of records for the sole purpose of extracting information for a demographic or statistical study in which no person can be identified.

10.10: Complaint

(1) Any person may file a complaint with the chairperson of the Research Review Committee about a research project approved by the Committee.

(2) Upon receipt of a complaint, the chairperson of the Committee shall notify promptly the investigator(s) of the research that a complaint has been filed. The chairperson also shall conduct a preliminary investigation and refer the complaint to the Committee for further review and action if he or she determines that such referral is warranted.

(3) The Committee, as part of its investigation of a complaint, shall provide the complainant and the investigator(s) of the research the opportunity to present relevant information to the Committee. Within 30 days of receiving the complaint, the Committee shall take such action as it determines appropriate, including, but not limited to:

(a) termination of the research project;

(b) imposition of additional conditions on the research;

(c) temporary suspension of the research pending further investigation or other action; or

(d) dismissal of the complaint;

(4) The Committee shall give prompt notification to the complainant and the investigator(s) of its action. The Committee shall keep written records of all complaints, investigation of complaints, action taken by the Committee and reasons for such action.

(5) Any action taken by the Committee on a complaint is final and not subject to further review, judicial or otherwise.

10.11: Funding for Research

(1) A research project which provides for compensation of any participant may not be approved unless:

(a) the compensation is received from or passes through an organization which has agreed that all its fiscal records pertaining to such research shall be subject to audit by the Department of Mental Retardation at any time; or

(b) the compensation is received from the Commonwealth of Massachusetts.

(2) 115 CMR 10.11 does not apply where the compensation consists solely of funds from a grant from a federal government agency or authority.

10.12: Sanctions

In the event of violation of the human rights of participants, or in the event that the research is not being conducted in accordance with applicable statutes, regulations or the requirements of the Committee, the Commissioner may impose appropriate sanctions. These may include the immediate suspension or termination of the research project and taking or seeking disciplinary action against project personnel.

REGULATORY AUTHORITY

115 CMR 10.00: M.G.L. c. 19B, §§ 1, 14 and 18; M.G.L. c. 123B, § 2.

NON-TEXT PAGE